

### **III. Remarks**

#### **A. Status of the Application**

Claims 1-30 and 37-44 will be pending after entry of the present paper. Claims 1-39 were previously pending, of which claims 11, 12, and 31-36 were previously withdrawn for being directed to a non-elected species. Withdrawn claims 31-36 are canceled by the present paper without prejudice to or disclaimer of the subject matter therein. New claims 40-44 are added by the present paper. Support for the claim amendments and new claims can be found at least in paragraphs [0121]-[0140] and Figs. 14-17. No new matter is added by the amendments or new claims. Reconsideration of claims 1-10, 13-30, and 37-44 is requested in light of the above-amendments and the following remarks.

#### **B. Examiner Interview**

Applicants appreciate the courtesies extended by the Examiner during the telephone interview on December 2, 2009. Generally, the rejections based on the Marnay application and Cauthen patent set forth in the Office Action were discussed. No exhibits were shown in the interview. The Examiner and Applicants' representative generally agreed on the differences between the cited references and Applicants' invention. Accordingly, Applicants' representative agreed to amend the claims to better clarify these differences. Thus, the amendments presented above are consistent with the differences discussed in the telephone interview.

#### **C. Claim Rejections – 35 U.S.C. § 103**

**Claims 1-10, 13-30, and 37-39** stand rejected under 35 U.S.C. §103(a) as being unpatentable over WO 01/01893 to Marnay et al. ("the Marnay application") in view of U.S. Patent No. 6,019,792 to Cauthen ("the Cauthen patent"). As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...

It is submitted that the examiner cannot factually support a *prima facie* case of obviousness with respect to claims 1-10, 13-30, and 37-39.

In *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that “a patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 1741 (emphasis added).

With respect to amended independent claim 1, even when combined the Marnay application and the Cauthen patent fail to disclose or suggest, “a first component, comprising ... a projection extending from a first articular surface, the projection being offset in an anterior direction relative to a first center point of the first articular surface; and a second component adapted to be engaged with the first component, comprising ... a recess formed in a second articular surface, the recess being offset in a posterior direction relative to a second center point of the second articular surface ... wherein engagement of the projection and the recess results in the second component being offset in the anterior direction relative to the first component thereby accommodating a spondylosed relationship between a first vertebra and a second vertebra adjacent to the first vertebra,” as recited. In that regard, neither the Marnay application nor the Cauthen patent discloses having a projection offset in an anterior direction and a recess offset in a posterior direction such that the first and second components are offset such that the prosthetic device accommodates spondylosed vertebrae.

As noted by the Examiner, the Marnay application fails to teach that the projection and recess can be located anywhere other than centrally. (Office Action, pg. 3). Further, while the Cauthen patent discloses that the location of the articulation means 24 “can be selectively varies to position the center of rotation of the articulation means 24 centrally, anteriorly, posteriorly, to

the left, to the right, or eccentrically (off-center in both the anterior/posterior direction and the left/right direction)”, there is no disclosure or suggest of having a projection offset in one direction (e.g., anteriorly) and a recess offset in the opposite direction (e.g., posteriorly). Rather, the Cauthen patent appears to teach that the projection and recess would be offset in the same direction in order to adjust the center of rotation of the articulation means. Accordingly, even when combined the Marnay application and the Cauthen patent fail to disclose or suggest all of the recited features of independent claim 1. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to independent claim 1. Claims 2-10 depend from and further limit independent claim 1. Therefore, Applicants respectfully request that the § 103 rejection of claims 1-10 be withdrawn.

With respect to independent claim 13, even when combined the Marnay application and the Cauthen patent fail to disclose or suggest, “a first component ... and a second component ... wherein one of the first and second components comprises a projection and the other of the first and second components comprises a recess, the projection and recess being adapted to engage one another, and wherein at least one of the projection and the recess is offset relative to the first component or the second component such that when the projection and the recess are engaged with one another the first and second components are offset with respect to one another to accommodate a spondylosed relationship between the first and second vertebrae.” As discussed above with respect to claim 1, the Marnay application and the Cauthen application simply do not disclose or suggest such an offset relationship of the components. Accordingly, a *prima facie* case of obviousness has not been established with respect to independent claim 13. Claims 14-30 depend from and further limit claim 13. Therefore, Applicants respectfully request that the § 103 rejection of claims 13-30 be withdrawn.

With respect to independent claim 37, even when combined the Marnay application and the Cauthen patent fail to disclose or suggest, “providing a prosthetic device having a first articular component with an offset projection, and a second articular component with an offset recess adapted to engage with the offset projection such that the first articular component is offset relative to the second articular component to accommodate a spondylosed relationship, longitudinally inserting the first articular component into a disc space such that a portion of the

first articular component engages a first vertebra, and longitudinally inserting the second articular component into the disc space such that the offset projection and offset recess are engaged with one another and such that a portion of the second articular component engages a second vertebra, the second vertebra being adjacent to and in a spondylosed relationship with the first vertebra.” In the context of the recited method of claim 37, neither the Marnay application nor the Cauthen patent even mentions spondylosed vertebrae, let alone treating spondylosed vertebrae. Further, as discussed above, even when combined the Marnay application and the Cauthen patent fail to disclose or suggest a prosthetic device having an offset projection and offset recess as required of the prosthetic device of claim 37. Accordingly, for at least these reasons a *prima facie* case of obviousness cannot be established with respect to independent claim 37. Claims 38 and 39, as well as new claim 40, depend from and further limit claim 37. Therefore, Applicants respectfully request that the § 103 rejection of claims 37-39 be withdrawn.

#### **D. New Claims**

New claims 40-44 recite additional combinations of features that are not disclosed or suggested by the Marnay application and the Cauthen application. For example, new independent claim 41 requires:

41. (Currently Amended) A prosthetic device for positioning within an intervertebral space between a first vertebra and a second vertebra, comprising:
  - a first component comprising:
    - a first engagement surface for securely engaging with the first vertebra, and
    - a first articular surface opposite the first engagement surface, the first articular surface having a projection extending therefrom, the projection being offset in a first direction relative to a first center point of the first component; and
  - a second component comprising:
    - a second engagement surface for securely engaging with the second vertebra, and
    - a second articular surface opposite the second engagement surface, the second articular surface including a recess, the recess being offset in a second direction relative to a second center point of the second component,

the second direction being substantially opposite the first direction, the recess sized and shaped to be movably engaged with the projection of the first component; wherein engagement of the projection and the recess results in the first center point of the first component being offset relative to the second center point of the second component such that the first and second components are offset with respect to one another.

Claims 42-44 depend from and further limit claim 41. Accordingly, Applicants submit that new claims 41-44 are also patentable over the cited references.

#### **IV. Conclusion**

Applicants believe that all matters set forth in the Office Action have been addressed and that claims 1-10, 13-30, and 37-44 are in condition for allowance. An early formal notice of allowance is requested.

The Office Action contains characterizations of the claims and the related art to which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in this or any other Office Action.

Should the Examiner deem that an interview with Applicants' undersigned attorney would expedite the prosecution of the present application, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.


Respectfully submitted,



Gregory P. Webb  
Registration No. 59,859

Date: 1-6-10  
HAYNES AND BOONE, LLP  
Customer No. 46333  
Telephone: 972-739-8641  
Facsimile: 214-200-0853

I hereby certify that this correspondence is being filed with  
the United States Patent and Trademark Office via EFS-Web  
on 1-6-10.

  
Gayle Conner